K121278

ATTACHMENT 3

5.0 510 (k) SUMMARY

DEC 18 2012

A. Submitted by:

- **Submitters name and address:**
  Hermes Medical Solutions AB
  Skeppsbron 44
  111 30 Stockholm
  Sweden

- **Submitters telephone number**
  Phone: +46 8 19 03 25
  Cell: +46 708 19 03 08
  Fax: +46 8 18 43 54
  E-mail: joakim.arwidson@hermesmedical.com

- **Contact person**
  Joakim Arwidson
  Quality Manager
  Hermes Medical Solutions AB
  Skeppsbron 44
  111 30 Stockholm
  Sweden

- **Registration number**
  9710645

B. Preparation date:
2012-04-16

C. Proprietary/Trade name, Common name, Classification name:

- **Proprietary/Trade name**
  Hermes Medical Imaging Suite v5.2

- **Common name**
  Image processing systems

- **Classification name**
  Emission Computer Tomography System, Class II, 21CFR892.1200

D. Legally marketed device (predicate device):
Following legally marketed devices has been used for comparison.

- HERMES HDAQ Acquisition Station and Hermes Workstation (K002782)
- HERMES HDAQ Acquisition Station and Hermes Workstation (K021656)
- e.cam computer / e.soft workstation (K023190)
- Xeleris 2 processing and review workstation (K051673)

E. Description of the device that is subject of this premarket notification:
The base product design of Hermes Medical Imaging Suite is the same as for the Hermes Workstation (K021656, K002782), except that some third party applications and the acquisition

station is removed and addition of two applications, as described in the 510(k) submission. The Hermes Medical Imaging Suite provides software applications used to process, display, analyze and manage nuclear medicine and other medical imaging data transferred from other workstation or acquisition stations.

F. Intended use:
HERMES Medical Imaging suite that provides software applications used to process, display, analyze and manage nuclear medicine and other medical imaging data transferred from other workstation or acquisition stations.

G. Technological characteristics:
The proposed device Hermes Medical Imaging Suite has the same technological characteristics as the original device and the same indication for use, except that some third party applications and the acquisition station is removed and addition of two applications, as described in the 510(k) submission.

H. Testing:
The tests for verification and validation followed Hermes Medical Solutions AB design controlled procedures. The Risk analysis was completed and risk control implemented to mitigate identified hazards. The testing results supports that all the software specifications have met the acceptance criteria.

I. Substantially Equivalent/Conclusions:
The proposed device Hermes Medical Imaging Suite and the predicate devices Nuclear Diagnostics HERMES HDAQ Acquisition Station and Hermes Workstation (K021656, K002782) have the same indication for use, except that the acquisition station is removed from the HERMES Medical Imaging Suite.

The proposed device will use similar technology and fundamental concepts and operation are also the same, as described in the 510(k) submission.

Comparisons were made between Hybrid Display and e.cam computer / e.soft workstation (K023190), and between Hybrid Recon™ and Xeleris 2 processing and review workstation (K051673). The results showed a good compliance.

In summary, the HERMES Medical Imaging Suite, described in this submission is, in our opinion, substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 18, 2012

Mr. Joakim Arwidson
Quality Manager
Hermes Medical Solutions AB
Skeppsbron 44
Stockholm, 11130
SWEDEN

Re: K121278
Trade/Device Name: HERMES Medical Imaging Workstation
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS
Dated: November 1, 2012
Received: November 21, 2012

Dear Mr. Arwidson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris -S

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121278

Device Name: HERMES Medical Imaging Workstation

Indications For Use:

HERMES Medical Imaging suite that provides software applications used to process, display, analyze and manage nuclear medicine and other medical imaging data transferred from other workstation or acquisition stations.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Janine M. Morris -S

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K121278